

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION**

Lori Weinacker, <i>et al.</i> ,)	Civil Action No.: 6:16-cv-02286-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, <i>et al.</i> ,)	
Defendants.)	
Ennis Bagwell and Vickie Bagwell,)	Civil Action No.: 6:16-cv-02308-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	
Tina DeYoung Smith, <i>et al.</i> ,)	Civil Action No.: 6:16-cv-03131-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	
Thomas Fowler and Roseann Fowler,)	Civil Action No.: 6:16-cv-02307-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	
Earl Gilstrap and Laura Gilstrap,)	Civil Action No.: 6:16-cv-03132-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	
Felicia Johnson,)	Civil Action No.: 6:16-cv-03130-BHH
Plaintiff,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	
Melvin Mattison, <i>et al.</i> ,)	Civil Action No.: 6:16-cv-03128-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	
James Thomason and Kaye Thomason,)	Civil Action No.: 6:16-cv-03129-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	

Phillip Lamar West, <i>et al.</i> ,)	Civil Action No.: 8:16-cv-02688-BHH
Plaintiffs,)	
v.)	
Sorin Group Deutschland, GMBH, et al.,)	
Defendants.)	

**DEFENDANTS' LOCAL CIVIL RULE 26.03 DISCLOSURES AND PROPOSED
DISCOVERY PLAN**

Defendants Sorin Group Deutschland GMBH ("Sorin Deutschland") and Sorin Group USA, Inc. ("Sorin USA") (collectively, "Defendants"), by and through undersigned counsel, submit the following report pursuant to Fed. R. Civ. P. 26(f) and Local Civil Rule 26.03, D.S.C.¹:

I. RULE 26(F) CONFERENCE

Pursuant to Fed. R. Civ. P. 26(f), a telephonic meeting was held between the parties on Friday, January 6, 2017, and was attended by: Stephen Welch on behalf of the West plaintiffs, Blake Smith and Ashlee Winkler on behalf of the remainder of the plaintiffs, and Linda Svitak and Susan McWilliams on behalf of the defendants.

II. RULE 26(f)(1-4) RESPONSES

(1) What changes should be made in the timing, form, or requirement for disclosures under Rule 26(a), including a statement as to when disclosures under Rule 26(a)(1) were made or will be made?

Pursuant to the parties' Joint Motion to Extend Rule 26 Reporting Requirements and to Coordinate Pre-Trial Discovery ("Joint Motion") and the Court's October 31, 2016, Order granting the Joint Motion, the parties have agreed that Rule 26 disclosures should be made no later than January 9, 2017, with the exception of the exchange of documents pursuant to Rule(a)(1). Defendants will make their documents pursuant to Rule 26(a)(1)(A)(ii) available on or before January 30, 2017. Moreover, the parties have agreed and the Court has ordered that these matters should be coordinated for pre-trial discovery. Accordingly, the form of the parties'

¹ Due to the number of different plaintiffs, they will be filing their Local Civil Rule 26.03 responses separately.

Rule 26 disclosures will be changed to make appropriate disclosures both generally and as to each of the matters that have been consolidated.

(2) The subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused upon particular issues.

Defendants believe that discovery will be needed on the following subjects:

- a. each Plaintiff's complete medical history for the time period from five years before the date of the surgery to the present time, if applicable, including any and all pre-existing medical conditions;
- b. all facts surrounding each Plaintiff's activities before and after the surgical procedure during which each Plaintiff claims to have been exposed to a Sorin 3T heater-cooler unit;
- c. the design, manufacture, and sale of the Sorin 3T heater-cooler units at issue; negligence issues of intervening third parties; negligence issues related to each Plaintiff; abuse or misuse of the Sorin 3T heater-cooler unit at issue; and
- d. the medical care received by each Plaintiff before and after the surgery at which the Sorin 3T heater-cooler unit was used.

Defendants expressly reserve the right to supplement this response or to seek additional discovery as may be deemed appropriate. The parties have agreed that fact discovery should be completed no later than January 8, 2018, with the understanding that, if unexpected issues arise, the parties may need additional time for discovery. The parties do not believe that discovery should be conducted in phases or be limited to, or focused upon, particular issues.

(3) What changes should be made in the limitations on discovery imposed under these rules or by local rule, and what other limitations should be imposed.

The parties agree that no limitations on discovery other than those already contained in

the Federal Rules of Civil Procedure need be imposed. Absent agreement of counsel, discovery requests will be limited to 25 interrogatories per party and plaintiffs' requests will be consolidated into a total of 25 interrogatories per defendant.

(4) Any other orders that should be entered by the court under Rule 26(c) or under Rule 16(b) and (c).

Contemporaneously with these Rule 26.03 disclosures, the parties will file a proposed Amended Conference and Scheduling Order for the Court's consideration. Additionally, Defendants intend to seek a protective order to preserve the confidentiality of Defendants' trade secrets and proprietary information pursuant to Rule 26(c)(1)(G) and will be circulating a proposed protective order to counsel for the plaintiffs for consideration shortly.

III. LOCAL CIVIL RULE 26.03 DISCLOSURES

Defendants, by and through their undersigned counsel, submit the following report pursuant to Local Civil Rule 26.03, D.S.C.:

(1) A short statement of the facts of the case.

This is a product liability action in which Plaintiffs allege that they were exposed to *M. abscessus* bacteria during cardiac bypass surgeries at Greenville Health System Hospital through the use of a Sorin 3T Heater/Cooler System. Plaintiffs have brought a number of claims, including negligence, strict product liability, breach of express and implied warranties, negligent misrepresentation, misrepresentation by omission, violation of S.C. Unfair Trade Practices Act, wrongful death, survival, loss of consortium, and actual and punitive damages. Defendants deny all claims.

(2) The names of the fact witnesses likely to be called by the party and a brief summary of their expected testimony.

Defendants state that they are likely to call certain fact witnesses to testify to general facts in multiple cases, but that they may also call case-specific fact witnesses in individual

cases. Defendants categorize the fact witnesses they may call at trial accordingly as follows:

a. General fact witnesses

1. Select employees and records custodians of Greenville Health System Hospital, 701 Grove Road, Greenville, SC 29605; (864) 455-7000. Such individuals may have discoverable information regarding any Sorin 3T heater-cooler units in use; the cleaning and disinfection procedures applicable to these units; the cleaning and disinfection protocols followed for these units over time; the condition of these units over time; the configuration of and conditions in the operating rooms where cardiac surgery occurred during the relevant time period; the investigations into potential risk for infection with NTM or its subspecies; differences in potential risk for NTM infection based on patient, hospital, or surgery factors; patient notification procedures that have been instituted; any screening or medical interventions followed; and information about any other heater-cooler devices used during the relevant time period.

2. Thierry Dupoux, Vice President Quality Assurance, c/o Defendants' counsel. Mr. Dupoux may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin 3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

3. Christian Peis, Director Quality Assurance, c/o Defendants' counsel. Mr. Peis may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin 3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

4. Bryan Olin, Senior Vice President Clinical, Quality, and Regulatory Affairs, c/o Defendants' counsel. Mr. Olin may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin 3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

5. Shanna Schmidt, Product Manager, c/o Defendants' counsel. Ms. Schmidt may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin 3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

6. Other current and former employees of either Defendant may have information concerning the design, development, testing, regulatory history, compliance, quality assurance, manufacturing, marketing, and sales of the Sorin 3T Systems alleged to have been used in Plaintiffs' surgeries. Such employees should be contacted through Defendants' counsel only.

b. Fact witnesses specific to Plaintiffs Ennis and Vickie Bagwell

1. Plaintiff Ennis Bagwell. Mr. Bagwell will have knowledge of his claimed injuries and damages, his medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to nontuberculous mycobacteria ("NTM"), and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

2. Plaintiff Vickie Bagwell. Ms. Bagwell will have knowledge of her claimed injuries and damages, Mr. Bagwell's medical and health condition before and after cardiac surgery, any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

3. Mr. Bagwell's treating physicians. Such individuals may have discoverable information regarding Mr. Bagwell's medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

a. Scott Johnson, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

c. Fact witnesses specific to Plaintiff Tina DeYoung-Smith

1. Plaintiff Tina DeYoung-Smith. Ms. DeYoung-Smith will have knowledge of her claimed injuries and damages and may have knowledge of Ms. Marion DeYoung's medical and health condition before and after cardiac surgery, communications with her healthcare providers and hospitals, communications

with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, communications with any governmental investigators, and communications with Defendants.

2. Ms. DeYoung's treating physicians. Such individuals may have discoverable information regarding Ms. DeYoung's medical and health condition before and after cardiac surgery, the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

d. Fact witnesses specific to Plaintiffs Thomas and Rosann Fowler

1. Plaintiff Thomas Fowler. Mr. Fowler will have knowledge of his claimed injuries and damages, his medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

2. Plaintiff Rosann Fowler. Ms. Fowler will have knowledge of her claimed injuries and damages, Mr. Fowler's medical and health condition before

and after cardiac surgery, any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

3. Mr. Fowler's treating physicians. Such individuals may have discoverable information regarding Mr. Fowler's medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

e. Fact witnesses specific to Plaintiffs Earl and Laura Gilstrap

1. Plaintiff Earl Gilstrap. Mr. Gilstrap will have knowledge of his claimed injuries and damages, his medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he

requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

2. Plaintiff Laura Gilstrap. Ms. Gilstrap will have knowledge of her claimed injuries and damages, Mr. Gilstrap's medical and health condition before and after cardiac surgery, any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

3. Mr. Gilstrap's treating physicians. Such individuals may have discoverable information regarding Mr. Gilstrap's medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

- a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

f. Fact witnesses specific to Plaintiff Felicia Johnson

1. Plaintiff Felicia Johnson. Ms. Johnson will have knowledge of her claimed injuries and damages, her medical and health condition before and after

cardiac surgery, the nature and extent of her current impairment (if any), any current symptoms of infection, communications with her healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether she requires any treatment for her alleged injuries, communications with any governmental investigators, and communications with Defendants.

2. Ms. Johnson's treating physicians. Such individuals may have discoverable information regarding Ms. Johnson's medical and health condition before and after cardiac surgery, the nature and extent of her current impairment (if any), the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

g. Fact witnesses specific to Plaintiff Melvin Mattison

1. Plaintiff Melvin Mattison. Mr. Mattison will have knowledge of his claimed injuries and damages and may have knowledge of Ms. Ella Mae Mattison's medical and health condition before and after cardiac surgery, communications with her healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to

NTM, and the means for this exposure, communications with any governmental investigators, and communications with Defendants.

2. Ms. Mattison's treating physicians. Such individuals may have discoverable information regarding Ms. Mattison's medical and health condition before and after cardiac surgery, the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

h. Fact witnesses specific to Plaintiffs James and Kaye Thomason

1. Plaintiff James Thomason. Mr. Thomason will have knowledge of his claimed injuries and damages, his medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

2. Plaintiff Kaye Thomason. Ms. Thomason will have knowledge of her claimed injuries and damages, Mr. Thomason's medical and health condition before and after cardiac surgery, any current symptoms of infection,

communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

3. Mr. Thomason's treating physicians. Such individuals may have discoverable information regarding Mr. Thomason's medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

- a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

i. Fact witnesses specific to Plaintiff Lori Weinacker

1. Plaintiff Lori Weinacker. Ms. Weinacker will have knowledge of her claimed injuries and damages and may have knowledge of Mr. Henry Weinacker's medical and health condition before and after cardiac surgery, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, communications with any governmental investigators, and communications with Defendants.

2. Mr. Weinacker's treating physicians. Such individuals may have discoverable information regarding Mr. Weinacker's medical and health condition before and after cardiac surgery, the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

j. Fact witnesses specific to Plaintiffs Phillip Lamar West and Karen Austin

1. Plaintiff Phillip Lamar West. Mr. West will have knowledge of his claimed injuries and damages, his medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

2. Plaintiff Karen Austin. Ms. Austin will have knowledge of her claimed injuries and damages, Mr. West's medical and health condition before and after cardiac surgery, any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited NTM, and the means

for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

3. Mr. West's treating physicians. Such individuals may have discoverable information regarding Mr. West's medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. Such treating physicians may include, but not be limited to:

- a. Barry Davis, MD
890 W. Faris Road
Greenville, SC 29605
(864) 455-6800

Defendants expressly reserve the right to supplement this response. By way of further response, Defendants incorporate by reference any and all witnesses named by any Plaintiff and expressly reserve the right to call such witnesses.

(3) The names and subject matter of expert witnesses (if no witnesses have been identified, the subject matter and field of expertise should be given as to experts likely to be offered).

Defendants state that no expert witnesses have been disclosed in these matters to date. However, Defendants anticipate that expert witnesses in various fields, including engineering and medicine, will be required to address issues related to the design and manufacture of the Sorin 3T heater-cooler unit, general and specific causation, and the medical conditions and claimed injuries of the Plaintiffs.

(4) A summary of the claims or defenses with statutory and/or case citations supporting the same.

a. Failure to State a Claim—For the defense of failure to state a claim upon which relief can be granted, Defendants crave reference to Fed. R. Civ. P. 12(b)(6).

b. Lack of Proximate Causation—For the defense that Plaintiffs’ causes of action are barred because the devices at issue in this case, manufactured by Defendants, were not the proximate cause of Plaintiffs’ alleged injuries, Defendants crave reference to *Graves v. CAS Med. Sys., Inc.*, 735 S.E.2d 650 (S.C. 2012); *Jackson v. Bermuda Sands, Inc.*, 677 S.E.2d 612 (S.C. App. 2009); *Rife v. Hitachi Const. Mach. Co., Ltd.*, 609 S.E.2d 565 (S.C. App. 2005); and others in this line of well-established case law.

c. Non-Defective Product—For the defense that Plaintiffs’ causes of action are barred because the devices at issue in this case, manufactured by Defendants, were not defective when they left the possession of Defendants or at any other relevant time, Defendants crave reference to *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244 (4th Cir. 1999) (S.C. law); *Graves v. CAS Med. Sys., Inc.*, 735 S.E.2d 650 (S.C. 2012); *Phillips v. S.C. State Univ.*, No. 2005-UP-320, 2005 WL 7084045 (S.C. App. May 12, 2005); *Correa v. Bon Secours St. Francis Xavier Hosp., Inc.*, 2013 WL 5925733 (S.C. Com. Pl. April 26, 2013); and other case law on this well-established defense.

d. Product Not Unreasonably Dangerous—For the defense that Plaintiffs’ causes of action are barred because the devices at issue in this case, manufactured by Defendants, were neither defective nor unreasonably dangerous and were suitable for the purpose for which they were intended, Defendants crave reference to *Graves v. CAS Med. Sys., Inc.*, 735 S.E.2d 650 (S.C. 2012); *Jackson v. Bermuda Sands, Inc.*, 677 S.E.2d 612

(S.C. App. 2009); *Rife v. Hitachi Const. Mach. Co., Ltd.*, 609 S.E.2d 565 (S.C. App. 2005); and others in this line of well-established case law.

e. Abuse, Misuse, and Improper Use of Product—For the defense that Plaintiffs’ causes of action are barred to the extent that the devices were abused, misused, or improperly used, Defendants crave reference to S.C. Code Ann. § 15-73-20; and *Marchant v. Mitchell Distrib. Co.*, 240 S.E.2d 511 (S.C. 1977); *Hilliard v. Manitowoc Co.*, 61 F.3d 900 (4th Cir. 1995) (S.C. law); and other well-established case law regarding this defense.

f. Adequate Warnings—For the defense that the devices at issue in this case were distributed with adequate and sufficient warnings, Defendants crave reference to *Phelan v. Synthes (U.S.A.)*, 35 Fed. App’x 102 (4th Cir. 2002) (S.C. law), and others in this line of well-established case law.

g. No Misrepresentation—For the defense that Plaintiffs have failed to state claims for misrepresentation, Defendants crave reference to *Jimenez v. DaimlerChrysler Corp.*, 269 F.3d 439 (4th Cir. 2001) (S.C. law); *Ardis v. Cox*, 431 S.E.2d 267 (S.C. App. 1993); and others in this line of well-established case law.

h. State of the Art—For the defense that the devices at issue in these cases were in conformity with the state of the art for the design and production of such devices, Defendants crave reference to *Cohen v. Winnebago Ind., Inc.*, 210 F.3d 360 (4th Cir. 2000) (S.C. law); *Bragg v. Hi-Ranger, Inc.*, 462 S.E.2d 321 (S.C. App. 1995); and others in this line of well-established case law.

i. Industry Standards—For the defense that the devices at issue in these cases were designed, manufactured, tested, distributed sold, and delivered in

conformance with then-prevailing industry standards and tested pursuant to then-applicable governmental regulations and statutes, Defendants crave reference to *Cohen v. Winnebago Ind., Inc.*, 210 F.3d 360 (4th Cir. 2000) (S.C. law); *Holst v. KCI Konecranes Int'l Corp.*, 699 S.E.2d 715 (S.C. App. 2010); *Bragg v. Hi-Ranger, Inc.*, 462 S.E.2d 321 (S.C. App. 1995); and others in this line of well-established case law.

j. Failure to Notify—For the defense that Plaintiffs failed to give Defendants proper notice of any alleged breach of implied warranty, Defendants crave reference to S.C. Code Ann. § 36-2-607.

k. Learned Intermediary/Sophisticated User Defense—For the defense that Defendants adequately and sufficiently warned Plaintiffs' treating physicians regarding the use of the devices at issue in these cases, Defendants crave reference to *Odom v. G.D. Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992) (S.C. law); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984) (S.C. law); *Bragg v. Hi-Ranger, Inc.*, 462 S.E.2d 321 (S.C. App. 1995); *Correa v. Bon Secours St. Francis Xavier Hosp., Inc.*, 2013 WL 5925733 (S.C. Com. Pl. April 26, 2013); and other case law on this well-established defense.

l. Mere Fact of Injury Insufficient—For the defense that injuries sustained by Plaintiffs, if any, in themselves would not be sufficient to impose liability upon Defendants, Defendants crave reference to *Graves v. CAS Med. Sys., Inc.*, 735 S.E.2d 650 (S.C. 2012); and other case law on this well-established defense.

m. Comparative Negligence—For the defense of comparative negligence, Defendants crave reference to *Thomasko v. Poole*, 561 S.E.2d 597 (S.C. 2002); *Scott v. Fortner*, No. 2014-UP-092, 2014 WL 2580087 (S.C. App. Mar. 5, 2014); and other case law on this well-established defense.

n. Intervening/Superseding Events— For the defense that Plaintiffs’ claims, in whole or in part, arise out intervening or superseding events, over which Defendants had no control and for which Defendants are not legally responsible, Defendants crave reference to *Young v. Tide Craft, Inc.*, 242 S.E.2d 671 (S.C. 1978); *Phillips v. S.C. State Univ.*, No. 2005-UP-320, 2005 WL 7084045 (S.C. App. May 12, 2005); and other case law on this well-established defense.

o. Comment K—For the defense that Plaintiffs are barred, in whole or in part, from asserting claims of liability against Defendants, Defendants crave reference to the doctrines contained in Restatement (Second) of Torts § 402(A).

p. Restatement (Third) of Torts—For the defense that Plaintiffs’ claims are barred, in whole or in part, Defendants crave reference to the doctrines of Restatement (Third) of Torts, Product Liability.

q. Apportionment—For the defense of apportionment, any damages recoverable from Defendants should be limited to the percentage of the relative degree of fault of Defendants as compared not only with other parties to this action, but also with other persons or entities not presently before this Court, pursuant to the South Carolina Contribution Among Tortfeasors Act, S.C. Code Ann. § 15-38-10, *et seq.*

r. Preemption—For the defense that Plaintiffs’ claims are barred, in whole or in part, to the extent that they are preempted, Defendants crave reference to federal law pursuant to the Supremacy Clause of the United States Constitution and the laws of the United States.

s. Absence of Willful and Wanton Conduct—For the defense that Defendants’ conduct was neither willful, wanton, nor reckless, thereby precluding an

award of punitive damages, Defendants crave reference to *Longshore v. Saber Sec. Servs., Inc.*, 619 S.E.2d 5 (S.C. App. 2005); and others in this line of well-established case law.

t. Failure to State a Claim for Punitive Damages—For the defense that Plaintiffs have failed to state claims for punitive damages, Defendants crave reference to *Jimenez v. DaimlerChrysler Corp.*, 269 F.3d 439 (4th Cir. 2001) (S.C. law); *Carter v. R.L. Jordan Oil Co., Inc.*, 390 S.E.2d 367 (S.C. App. 1990); and others in this line of well-established case law.

u. Punitive Damages Unconstitutional—For the defense that Plaintiffs are not entitled to punitive damages because punitive damages are unconstitutional, Defendants crave reference to the Due Process and Equal Protection Clauses of the Fifth and Fourteenth Amendments of the United States Constitution, and Article I, § 3, and Article I, § 15, of the South Carolina Constitution; the Eighth Amendment of the U.S. Constitution and the same or similar provisions of the S.C. Constitution, including but not limited to, Article I, § 15, of the S.C. Constitution; the Fifth and Sixth Amendments of the U.S. Constitution and the same or similar provisions of the S.C. Constitution, including but not limited to, Article I, § 12, Article I, § 14, and Article I, § 23.

Defendant reserves the right to add additional defenses as the factual record is developed in the course of discovery and additional defenses become apparent.

(5) Absent special instructions from the assigned judge, the parties shall propose dates for the following listed in Local Rule 16.02.

a. Exchange of FED. R. CIV. P. 26(a)(2) expert disclosure; and

The parties agree to exchange expert disclosures as follows:

For the Plaintiff: February 12, 2018

For the Defendant: March 26, 2018

b. Completion of discovery.

The parties agree fact discovery shall be completed in this case by January 8, 2018, and expert discovery shall be completed by May 7, 2018.

(6) The parties shall inform the Court whether there are any special circumstances which would affect the time frames applied in preparing the scheduling order. See generally Local Civil Rule 16.02 (C) (Content of Scheduling Order).

The parties have agreed that, as of the current date, there are no special circumstances that would affect the time frames applied in preparing the scheduling order.

(7) The parties shall provide any additional information requested in the Pre-Scheduling Order (Local Civil Rule 16.01) or otherwise requested by the assigned judge.

No additional information has been requested as of this date.

s/Susan P. McWilliams

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Sorin Group Deutschland, GMBH,
and Sorin Group USA, Inc.*

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Columbia, South Carolina